



Diabetic Foot Ulcer Ecosystem

Case-study for STS Roundtable Sep 2017

Background to case-study

- ITI Scotland had £7.9m (\$10.5m) to fund the development of a technology platform that enables healthcare professionals to detect and diagnose infections in diabetes-related and other chronic wounds at the point of care.
- We completed a comprehensive review of point-of-care wound care practitioner requirements for an infection detection and diagnosis solution as well as the factors influencing its adoption in clinical and community environments.
- In addition, we examined:
 - the technology landscape for POC infection diagnostics
 - the competitive landscape
 - the status of research into host biomarker detection
 - The detailed health economic case in four markets (UK, US, DE, IN) for different DFU POC infection diagnostic technology platforms
 - Expert clinician / key opinion leader perspectives

Diabetic Foot Ulcer (DFU) infection ecosystem study

Study questions

ECOSYSTEM GROWTH OPPORTUNITY AND VALUE

What is the specific nature of the market opportunity for rapid point-of-care DFU infection diagnostics (by health market, size, growth projection, value, commercial and investment case)?

ECOSYSTEM DIVERSITY

How do we understand the diversity of ecosystem actors, especially their different values, resources, goals and contexts?

ECOSYSTEM RELATIONSHIPS AND INTERDEPENDENCIES

What hidden ecosystem segments exist that cut across common assumptions, definitions and levels?

VALUE FRAMES AND PROPOSITIONS

What diagnostic and related propositions (Value Frames) are most likely to be adopted and reimbursed by different health systems and ecosystem segments? How do we avoid overdesigning interventions and technologies?

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Study questions

ECOSYSTEM ADAPTATION AND DYNAMICS

What is the competitive threat and how is it likely to evolve and manifest? What is the status and likely development of biomarker technology? How will developments in adjacent ecosystems influence opportunity and adoption?

EMERGENT STRATEGY DESIGN

What is the optimum ecosystem strategy for intervention, and with what diagnostic concepts? How to evolve the market?

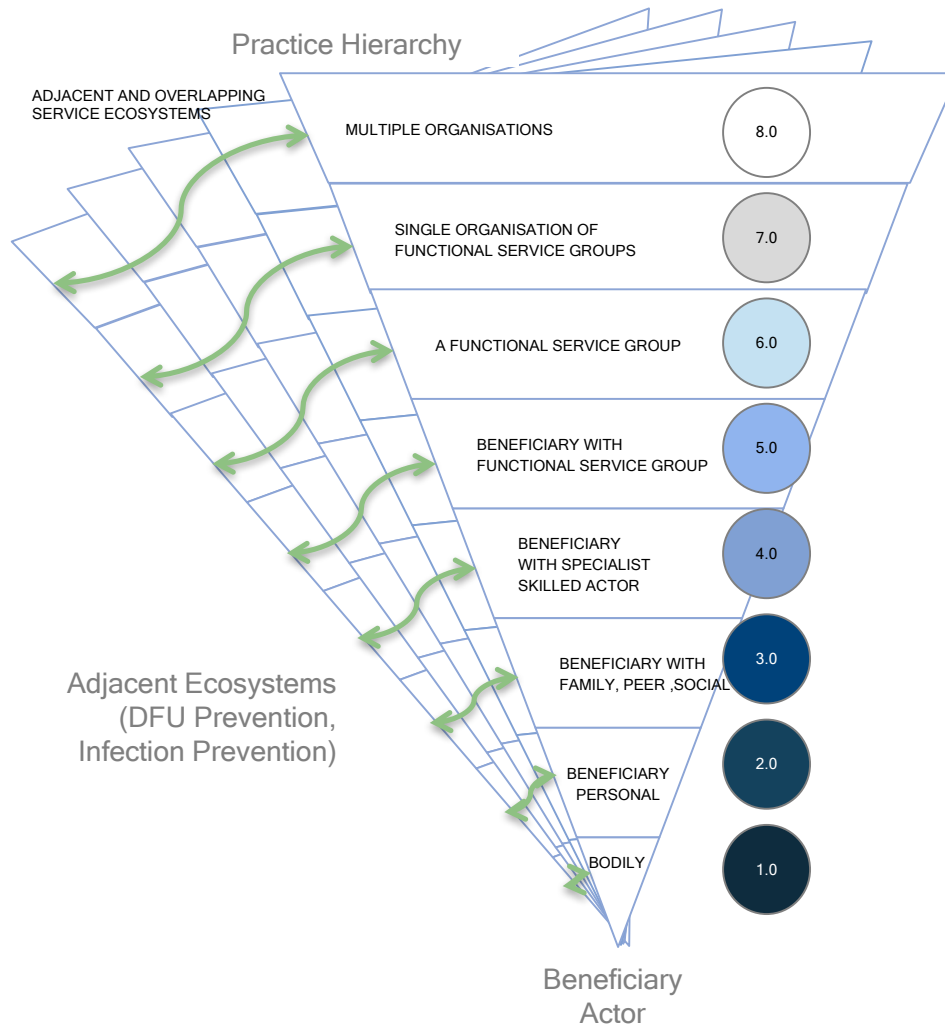
What are the risks and constraints to adoption in current practice? What is the technology strategy and roadmap?

CONCEPTS AND DEVELOPMENT SPECIFICATIONS

What are the segment user and functional requirements specifications of these concepts, to feed into development?

Treat Diabetic Foot Ulcer (DFU) infection ecosystem study

Primary Levels and Actors in focus



Level 8 - MULTIPLE ORGANISATION INTERACTIONS

Interactions between single healthcare organisations and regulators, reimbursement bodies, other payers and influencers

Level 7 - SINGLE ORGANISATION OF FUNCTIONAL SERVICE GROUPS

Interactions between diabetic foot clinics, outpatients, labs, community practices, wards and payers

Level 6 - FUNCTIONAL SERVICE GROUP

Diabetic foot clinic, podiatry clinic, outpatients, microbiology labs, surgery

Level 5 - BENEFICIARY WITH FUNCTIONAL GROUP

Patient interactions with specialist diabetic foot clinic, with GP practice, with podiatry clinic, with outpatients and with pharmacies; nurse interactions with GP practice, and with microbiology lab technicians

Level 4 - BENEFICIARY WITH SPECIALIST SKILLED ACTOR

Podiatrist, community and GP nurse, tissue viability nurse, doctor, diabetic nurse and diabetologist interactions with patients

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Study facts

- Completed in 12 week period
- Team of 3 Umio consultants
- Four distinct health markets: UK, US, Germany and India
- 65 x practitioner 40 minute 1:1 interviews on location
- 4 x on-site functional service group observations including discussions with patients
- 400 x 30 minute surveys followed by 100 x 5 minute follow-up surveys to capture performance data
- 6 x resource and cost data capture follow-up interviews
- 2 x co-creation workshops with KOLs and practitioners
- 4 x wound care KOL post-study validation interviews

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Study outputs

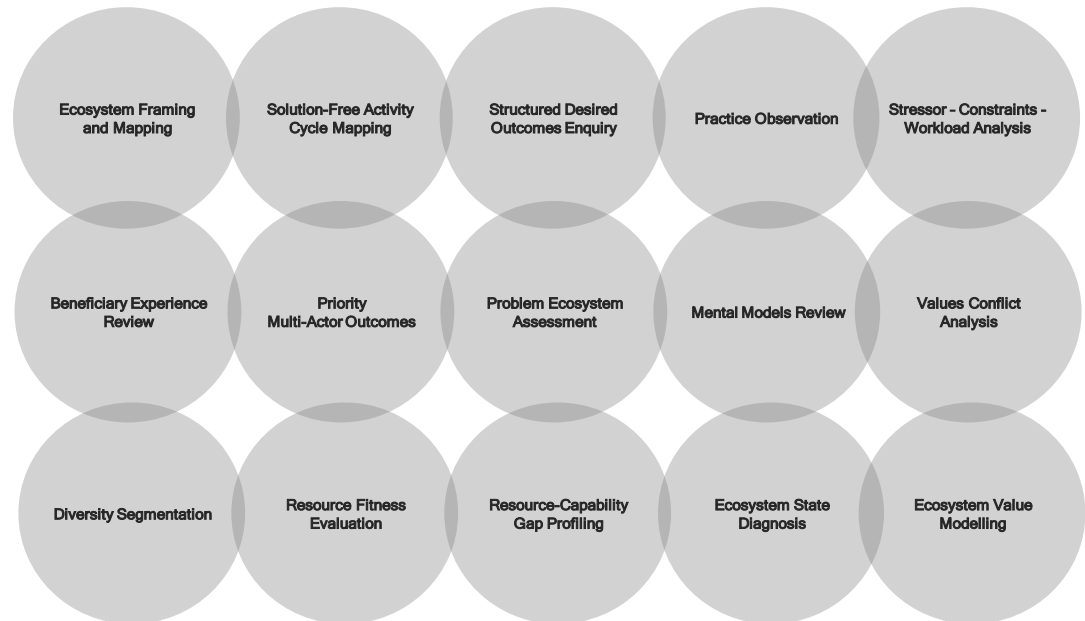
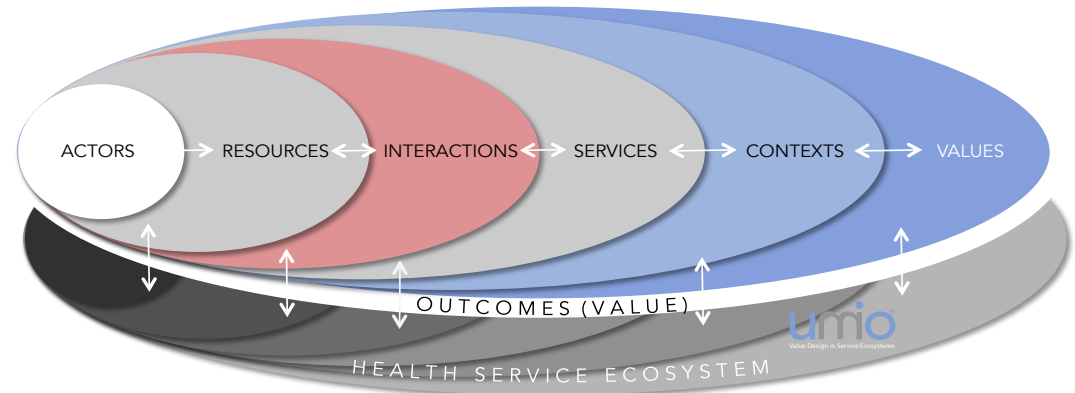
- One detailed service ecosystem map of patient, practitioner, microbiologist, payer interactions
- 175 practitioner and microbiologist contexts, unmet needs, desired outcomes and related capability gaps
- One problem situation specification (ecosystem trends and contexts)
- One biomarker development status review
- One holistic health ecosystem practitioner segmentation consisting of four hidden segments grouped by common values, risks, resources, unmet needs
- Eight distinct value propositions and technical concepts
- Four separate health economic models (MARKOV, QALY) for each health market and for 4 different ecosystem intervention scenarios
- A competitive analysis report exploring adjacent ecosystems
- One overall market access and growth strategy
- Four separate health market commercial cases including addressable market size, bill of materials, pricing and margin analysis
- One 60 page summary document of recommendations

Studying Practices in a Health Service Ecosystem

We deploy a variety of methods to study one or more of the practices at the different levels of a framed ecosystem.

The following sentence defines the “units of analysis” we study to enquire into practices and reveal problems, conflicts, opportunities, themes, patterns, relationships and priorities for improvement.

Influenced by values, human actors interact with tangible and intangible resources and each other to perform or obtain services in an effort to co-create outcomes (value) for a particular health ecosystem context



“Value in use” and technology evolution example



2000 BC+
Silk



10th Century
Cat Gut



1930s
Synthetic Polymers



1950s
Staple

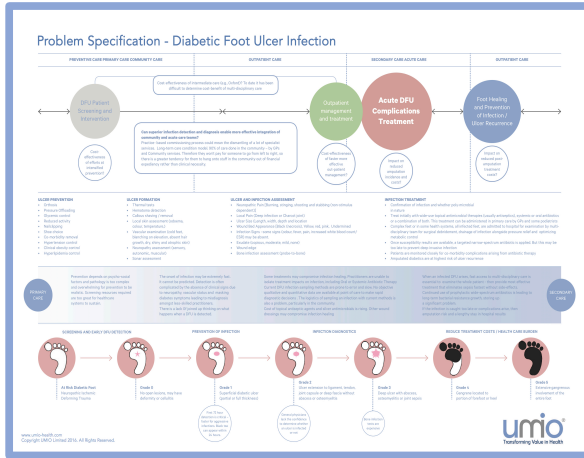


2000
Glue

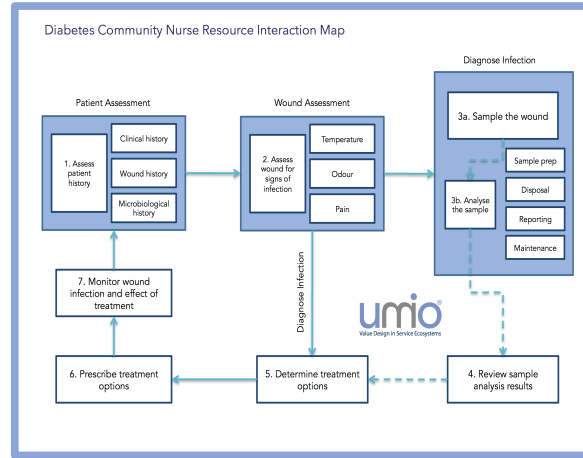
Close / Heal a Surgical Wound
[Example Goal and Market Definition]

Diabetic Foot Ulcer (DFU) Infection Ecosystem study

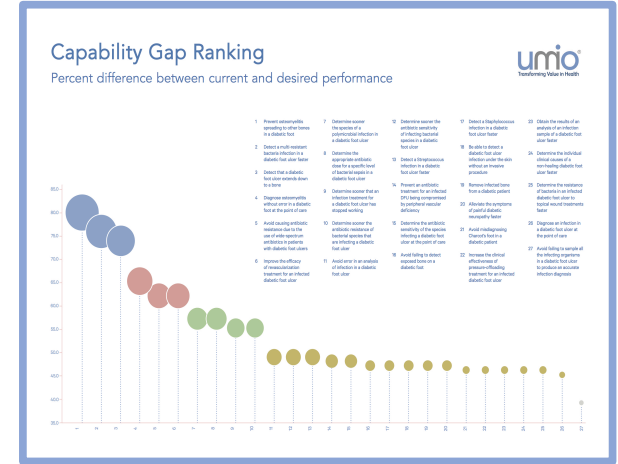
Examples of ecosystem and problem analysis, and co-creative outputs. (NB: More can be shown on request)



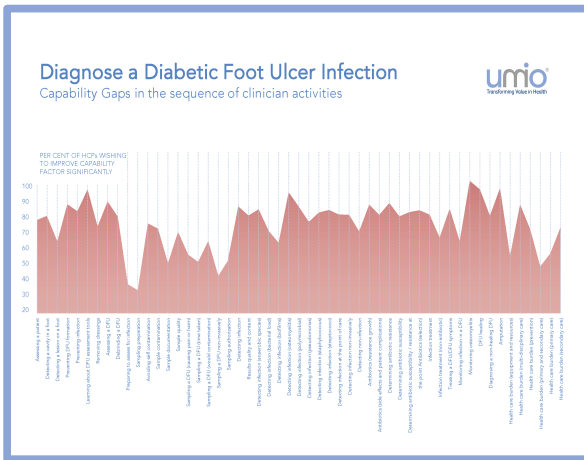
Ecosystem Problem Situation Map



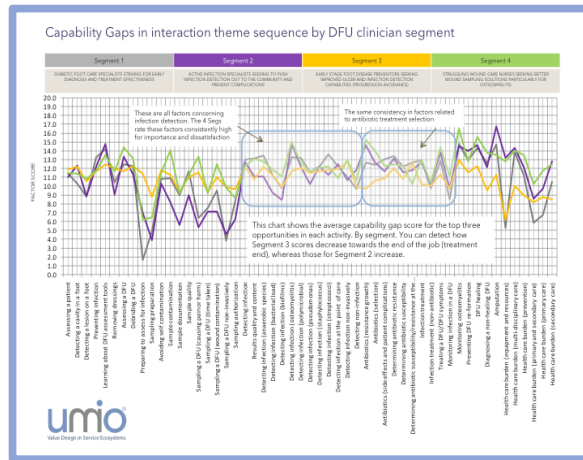
Actor-Resource Interactions Maps



Actor Resource-Capability Gap Ranking



Ecosystem Practices Performance Analysis



Ecosystem Segmentation and Practice Performance Analysis

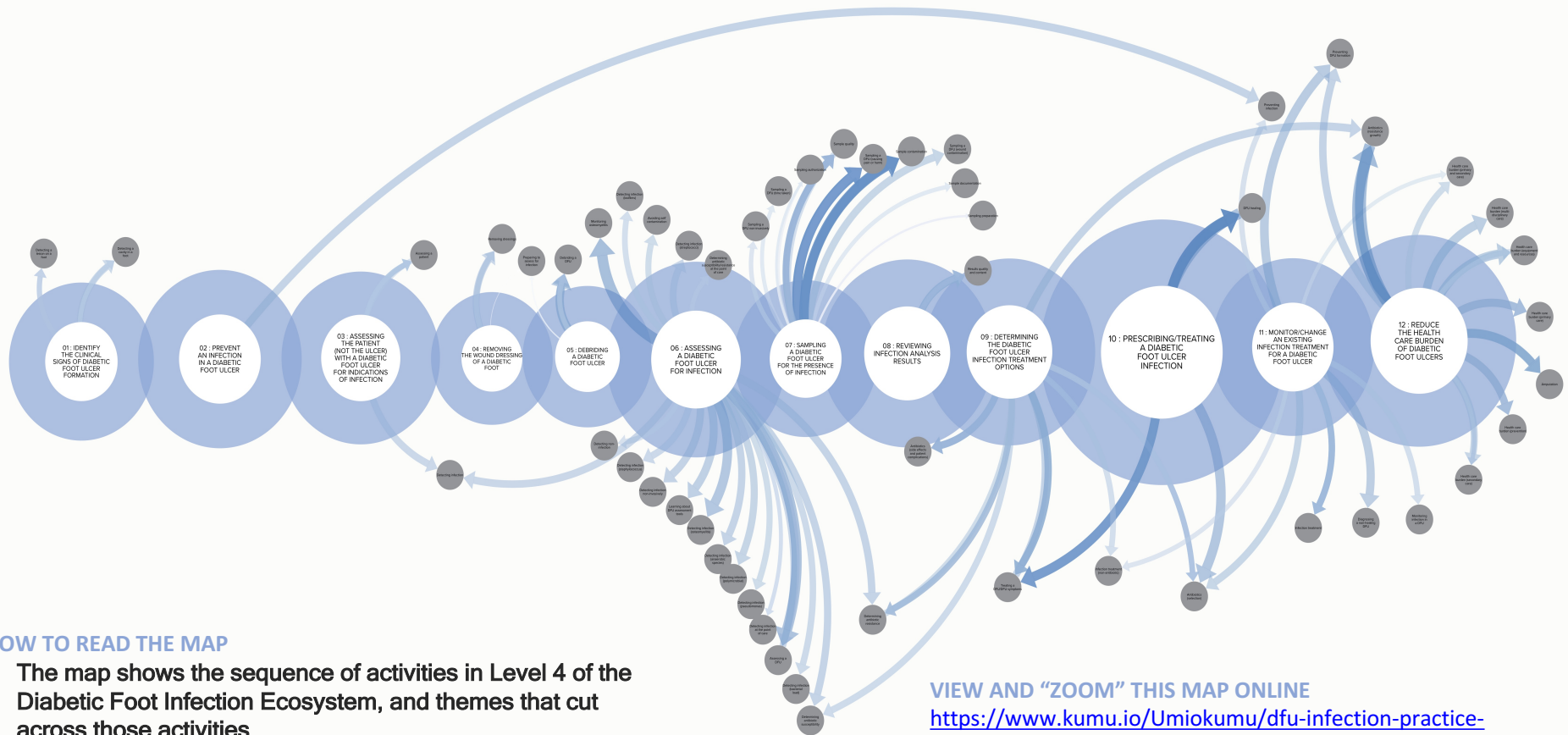
US resources by location and practitioner involvement by patient ulcer case type

Case Type	Cost \$	Cost €	w/hrs	CS1				NCS1										
				MJO	MSJO	MAJO	MAJO	MJO	MSJO	MAJO	MAJO							
WEEKS IN COMMUNITY																		
Pre hospitalisation	44	30.70	0.5	3	2	4	4	5	6	6	6	6	6	6	6	6	6	6
Community Nurse Visits	110	76.76	0.75	1	2	2	2	1	2	2	2	2	2	2	2	2	2	2
OP appointment	35	28.38	0.25	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Podiatrist appointments	50	34.89	1.1	2	2	2	2	0	1	1	1	1	1	1	1	1	1	1
Swab	38	26.53	0.2	1	2	2	2	0	1	1	1	1	1	1	1	1	1	1
Microbiologist (swab testing)	10	6.98	1.3	2	2	2	2	4	5	6	6	6	6	6	6	6	6	6
Dressings	100	69.76	1.1	2	2	2	2	0	1	1	1	1	1	1	1	1	1	1
Broad spectrum antibiotics (weeks course)	350	244.24	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Narrow spectrum oral antibiotics (weeks course)	140	115.14	0.12	0	2	5	8	8	2	5	8	8	8	8	8	8	8	8
WEEKS IN HOSPITAL																		
Hospitalisation and Recovery	145	115.14	0.15	0	14	22	43	0	14	22	43	43	43	43	43	43	43	43
Secondary Care Podiatrist (Inpatient)	552	348.92	1	0	4	8	8	0	4	8	8	8	8	8	8	8	8	8
Podiatrist appointments	0	0.00	0.0	0	4	8	8	0	4	8	8	8	8	8	8	8	8	8
Microbiologist (swab testing)	145	115.14	0.33	0	2	3	4	0	2	3	4	4	4	4	4	4	4	4
Diabetologist (inpatient)	145	115.14	0.15	0	14	35	56	14	35	56	56	56	56	56	56	56	56	56
Vascular Surgeon (inpatient)	145	115.14	0.33	0	3	5	5	0	3	5	5	5	5	5	5	5	5	5
X-ray	244	170.27	0	0	2	5	5	0	2	5	5	5	5	5	5	5	5	5
MRI scan	100	69.76	1	0	14	35	56	14	35	56	56	56	56	56	56	56	56	56
Dressings	100	69.76	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1
Broad Spectrum oral antibiotics	700	488.40	1	0	1	2	2	0	1	2	2	2	2	2	2	2	2	2
Narrow Spectrum IV antibiotics (weeks course)	350	244.24	1	0	1	2	3	0	1	2	3	3	3	3	3	3	3	3
Narrow Spectrum oral antibiotics (weeks course)	1000	1067.53	1	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0
Amputation - minor	3000	2093.05	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
Amputation - major	44	30.70	0.2	0	21	105	148	0	21	105	148	148	148	148	148	148	148	148
Hospital days	3000	2093.05	1	0	14	35	56	14	35	56	56	56	56	56	56	56	56	56
WEEKS IN OUTPATIENT/CLINICAL CARE																		
Outpatient / Clinical care	145	115.14	1	0	2	4	10	0	2	4	10	10	10	10	10	10	10	10
Repeat outpatient visit	44	30.70	0.2	0	8	26	40	0	8	26	40	40	40	40	40	40	40	40
Community Nurse visits	35	28.38	0.5	0	4	12	20	0	4	12	20	20	20	20	20	20	20	20
Community Podiatrist	10	6.98	1.0	0	8	24	56	0	8	24	56	56	56	56	56	56	56	56
Dressings	100	69.76	1.0	0	8	24	56	0	8	24	56	56	56	56	56	56	56	56

Intervention Cost and Value Model Single Country with Multi-Scenarios

Diabetic Foot Ulcer (DFU) Infection Ecosystem study

Opportunity map by activities and themes



HOW TO READ THE MAP

- The map shows the sequence of activities in Level 4 of the Diabetic Foot Infection Ecosystem, and themes that cut across those activities
- The bigger the blue circle, the greater the problem / degree of unmet need in the activity step
- The bluer or wider the connection, the greater the problem / opportunity in the theme

VIEW AND "ZOOM" THIS MAP ONLINE

<https://www.kumu.io/UmioKumu/dfu-infection-practice-opportunity-themes#map-ocMaNKAJ>

Diabetic Foot Ulcer (DFU) Infection Ecosystem study

Co-Creating Value Frames and Concepts

An **Umio Value Frame** is a thematic statement of possibility used to design multiple value propositions and ecosystem strategy and ultimately, to co-create or refine solutions.

Each Frame contains problem evidence, actor unmet needs, ecosystem resource gaps, constraints to overcome, emergent contexts, priority outcomes and problem paradoxes as well as measures of potential value, whether commercial and/or health system. An early business model design may be included in each Frame too.

Value Frames allow for further dialogue, collaboration and engagement around opportunities with both internal and external stakeholders.

Eight Value Frames were co-created in total for the DFU ecosystem study, each linked to the ecosystem segmentation. These are shown as P0-P7 on the next slide. Each is populated with a full URS/FRS and segment adoption model.

POC Antimicrobial Diagnostic Dashboard
A point-of-care antibiotic decision-making and monitoring system to enable enhanced evidence-based treatment selection and efficacy assessment

VALUE CASE DATA (€/US)	Market Size (Settings)	Market Spend (€/US)	Cost/Point per setting	Target Price per treatment	Cost Saving Target	Expected treatment
Yearly/Share	1.5Bn	1.5Bn	100k	€1/10000	0.5Bn	€1/40k

TARGET CUMULATIVE GAIN OPPORTUNITY MODEL

Reduce the time to care to detect or prevent infection in specific locations and within the ecosystem	81
Profile individual clinic settings for antibiotic use against central benchmark	83
Reduce the time to care to detect treatment problems for a community antibiotic treatment programme	83
Decrease the time to care to detect underlying conditions. Reduce the time to detect	77
Improve the quality of antibiotic use across multiple antibiotic classes	76

KEY FUNCTIONS AND FEATURES

- Generate the patient's best POC antibiotic use, including an action plan
- Data gathered on-site and distributed through decision-maker dashboard
- Potential to add an additional data to profile antibiotic use patterns based on location - disease incidence

SOLUTION CO-CREATION CONSIDERATIONS

- Secondary market absent to providing dashboard data to clinician
- Absent and/or competing models
- Means to integrate different types of data possible to gather and compare data from multiple stakeholders (e.g. clinician, pharmacist) to qualify new antibiotic decision-making
- All stakeholders that create antibiotic POC test evaluation and introduction to the market

ALIGNMENT VALUE FRAMES

World Market
Risk Market
Risk Disease
Risk Disease
Close to the Bone
Click to view the go to frame

BACTERIAL INFECTION TREATMENT ECOSYSTEM

PRIORITY CHAINS OUTCOMES AND KEY INDICATORS

Identify patient's antibiotic resistance due to ongoing use of antibiotic in antibiotic	81.2
Minimize the use of antibiotic resistance across the antibiotic use chain	76.2
Respond to unwanted changes in antibiotic use within the community	76.2
Reduce the volume of false positive antibiotic use for patients with DFU	86.2
Reduce ecosystem price performance benchmarking	86.8

CONTRACTS AND RISKS

- Transition to POC tests to be qualified staff will require their training and early involvement of specialists. Development on trials to be performed and take time to be integrated into local evidence and evidence management. Data quality and data use and use need to be qualified in context of a part of a treatment plan (clinical evidence / management)

STATISTICAL FIT AND ECOSYSTEM TRENDS CONTEXT

- Aligns with strategy to the increasingly antibiotic, de-escalated antibiotic and antibiotic resistance through use of antibiotic stewardship
- Most patients to be treated in the development of resources to use and POC diagnostic technologies. This is consistent with the opportunity to improve care and reduce antibiotic use in a fragmented ecosystem

POWER PROFILE AND JUSTIFICATION

- The role of the point-of-care antibiotic diagnostic technology could be used in the next 10 years, patients will need greater evidence of the efficacy of the test and the quality of the test and the test of the test
- Clinicians
- An antibiotic stewardship program provides the whole picture for best clinical outcomes and also requires ongoing education to influence and improve prescribing patterns

TARGET ACTION MOMENTS

- Engage clinicians that discuss treatment specialists for use seeking antibiotic stewardship and antibiotic resistance management. This is consistent with the strategy to use the patient management of antibiotic stewardship as a response with the growth of antibiotic resistance and the impact for the test
- Increase antibiotic stewardship programs
- Increase antibiotic stewardship with hospital settings
- POC Stewardship development and validation

SETTING PROFILE

HOME INSTITUTIONAL CARE SOCIAL CARE
OP DENTIST CLINIC TRANSFER
EMERGENCY INPATIENT EU

Value Frame For Home-Based Diabetic Osteomyelitis Detection
Qualitative POC indicator of chronic neuropathic osteomyelitis to reduce stress burden on community nurses arising from failure to detect and facilitate faster referral of patients to hospital / clinic for initial treatment, and reduce complication costs.

Market Size (Settings)	Market Size (€/US)	Cost/Point per setting	Target Price per treatment	Expected treatment
1.5Bn	1.5Bn	100k	€1/10000	€1/40k

TARGET CUMULATIVE GAIN OPPORTUNITY MODEL

Avoid osteomyelitis spreading to other bones in a diabetic foot (within 2 weeks)	81
Reduce the time to care to detect osteomyelitis in a diabetic foot (within 2 weeks)	83
Reduce the time to care to detect osteomyelitis in a diabetic foot after antibiotic therapy for a lower limb DFU (within 2 weeks)	77
Avoid osteomyelitis a bone sample when testing for osteomyelitis and will have more negative results from a POC of their antibiotic treatment	76
Reduce the time to care to detect osteomyelitis from a diabetic patient (within 20 minutes, able to perform in OP or community based setting)	76

KEY FUNCTIONS AND FEATURES

- Generate antibiotic resistance data for antibiotic use, including an action plan
- Data gathered on-site and distributed through decision-maker dashboard
- Potential to add an additional data to profile antibiotic use patterns based on location - disease incidence

SOLUTION CO-CREATION CONSIDERATIONS

- Secondary market absent to providing dashboard data to clinician
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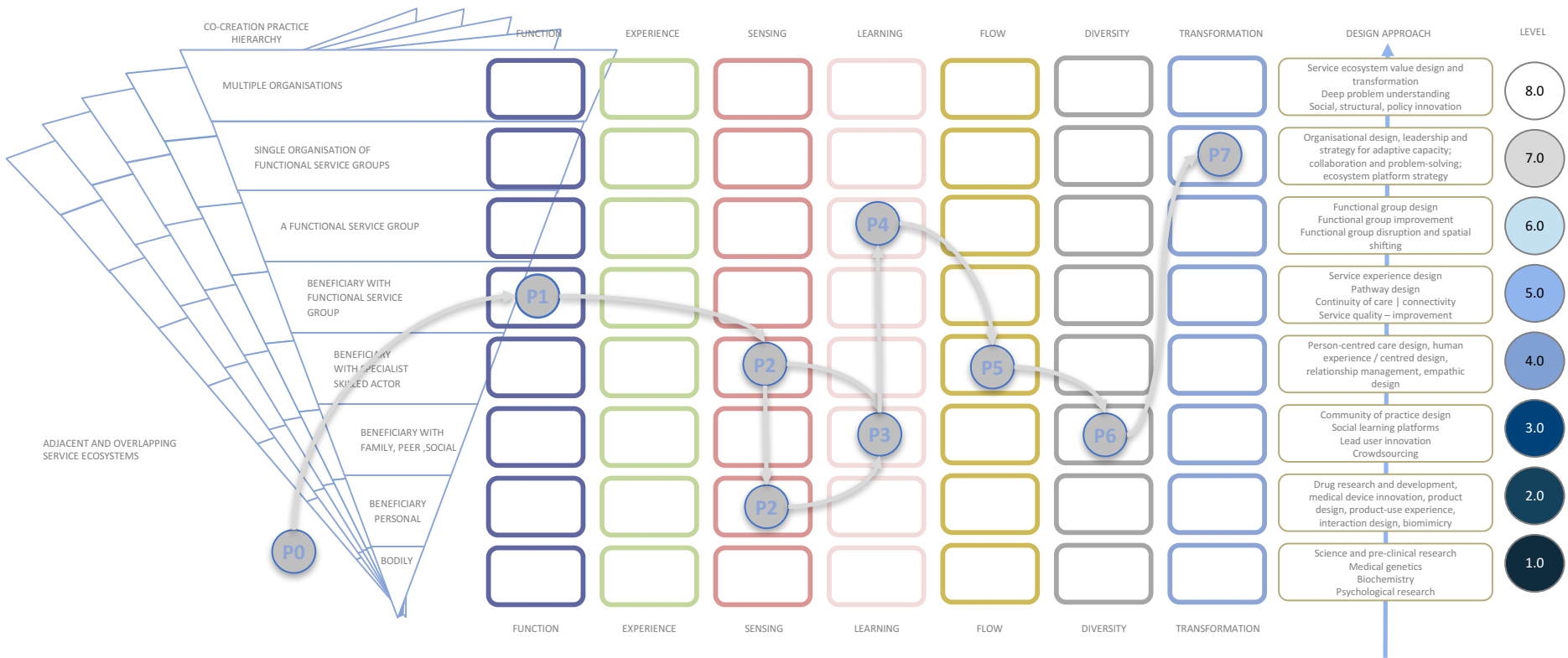
SETTING PROFILE

HOME INSTITUTIONAL CARE SOCIAL CARE
OP DENTIST CLINIC TRANSFER
EMERGENCY INPATIENT EU

Diabetic Foot Ulcer Infection Ecosystem study

The eight defined Value Frames and Strategic Value Design Map (high-level summary only)

- P0 POC DFU Detection and Infection Prevention
- P1 Near Patient Testing for MRSA
- P2 POC Qualitative Active Infection Detection (Yes / No)
- P3 POC Wound Healing Status Indication
- P4 POC Active Infection Detection with Speciation
- P5 POC Active Infection Detection with Speciation, Infection Management and Monitoring, Wound Management and Healing
- P6 POC Antibiotic Treatment Selection and Appropriability
- P7 POC Antimicrobial Diagnostic Dashboard



Diabetic Foot Ulcer Infection Ecosystem study

Study impact

- Umio opportunity data, segmentation, concept specifications, economic models, ecosystem plans and all insights were licensed by Scottish Enterprise (formerly ITI Scotland) to Mölnycke
- Mölnycke used the insights (supported by technology capabilities at Edinburgh University) to make its first step into the wound diagnostics market, investing in a new research and development team in Scotland in 2013, working with a consortium, PHYESTA
- They began work on developing a near-patient MRSA test for hospital admissions (concept P1). After two years, Detection was achieved in less than 1 hour straight from mock wound fluid without any extensive sample preparation steps. The sensitivity of detection was already near or above the level required for reliable diagnosis of infection.
- Formation of MHC Scotland also represents the first (and so far only) international inward investment to the Edinburgh BioQuarter which is an important part of Scottish Enterprise's delivery plan for economic benefit from the life sciences.



UMIO UK | EMEA

Bloxham Mill
Barford Road
Bloxham
Oxfordshire
United Kingdom
OX15 4FF

T: +44 (0)1295 724 539
E: info-eu@umio-health.com
W: www.umio-health.com

UMIO US

485 Massachusetts Avenue
Suite 300
Cambridge
02139-4018
UNITED STATES

Tel: +1 857-998-4050
E: info-us@umio-health.com